

REMARKS

This is a full and timely response to the non-final Office Action of June 21, 2006.

Reexamination, reconsideration, and allowance of the application and all presently pending claims are respectfully requested.

Upon entry of this First Response, claims 1-8, 10-13, 15-17, and 21-27 are pending in this application. Claims 1, 6-8, 10, 15-17, and 21 are directly amended herein, and claims 9, 14, and 18-20 are canceled without prejudice or disclaimer. Further, claims 22-27 are newly added. It is believed that the foregoing amendments add no new matter to the present application.

Response to §102 and §103 Rejections

“Anticipation under 35 U.S.C. §102 requires the presence in a single prior art disclosure of *each and every* element of the claimed invention.” *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747; 3 U.S.P.Q.3d 1766 (Fed. Cir. 1987). In order for a claim to be properly rejected under 35 U.S.C. §103, the combined teachings of the prior art references must suggest all features of the claimed invention to one of ordinary skill in the art. See, e.g., *In Re Dow Chemical Co.*, 837 F.2d 469, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988), and *In re Keller*, 642 F.2d 413, 208 U.S.P.Q. 871, 881 (C.C.P.A. 1981). In addition, “(t)he PTO has the burden under section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.” In this regard, “(o)bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of

references can be combined *only* if there is some suggestion or incentive to do so.” *ACS Hospital Systems, Inc., v. Montefiore Hospital*, 732 F.2d 1572, 1577; 221 U.S.P.Q. 929, 933 (Fed Cir. 1984).

Claim 1

Claim 1 presently stands rejected under 35 U.S.C. §102 as allegedly being anticipated by *Johnson* (U.S. Patent No. 4,191,125). Claim 1 reads as follows:

1. A phase change material, comprising:
a mixture of water and deuterium oxide wherein the mole fraction of deuterium oxide is selected to provide a desired phase change temperature ***in a range above zero degrees Celsius and below 3.8 degrees Celsius, wherein the mixture is positioned in close proximity to a biological material such that a temperature of the biological material is maintained near the desired phase change temperature.*** (Emphasis added).

Applicants respectfully assert that *Johnson* fails to disclose at least the features of claim 1 highlighted hereinabove. Thus, the 35 U.S.C. §102 rejection of claim 1, as amended, is improper.

In this regard, *Johnson* appears to disclose a “freeze indicator” that apparently uses a mixture of deuterium oxide and water to provide a material that freezes between negative (-) 4 degrees Celsius and 0 degrees Celsius. See column 2, lines 65-68. Thus, *Johnson* fails to disclose “a mixture of water and deuterium oxide wherein the mole fraction of deuterium oxide is selected to provide a desired phase change temperature in a range ***above zero degrees Celsius*** and below 3.8 degrees Celsius,” as recited by claim 1. (Emphasis added).

In addition, *Johnson* fails to indicate that the material of the “freeze indicator” is positioned close to a biological material. Thus, *Johnson* fails to disclose “wherein the mixture is positioned in close proximity to a biological material such that a temperature of the biological material is maintained near the desired phase change temperature,” as recited by claim 1.

For at least the above reasons, Applicants respectfully assert that the cited art fails to disclose each feature of pending claim 1. Therefore, the 35 U.S.C. §102 rejection of claim 1 should be withdrawn.

Claims 2-5 and 22-27

Claims 2 and 3 presently stand rejected in the Office Action under 35 U.S.C. §102 as allegedly being anticipated by *Johnson*. In addition, claim 4 presently stands rejected in the Office Action under 35 U.S.C. §103 as allegedly being unpatentable over *Johnson* in view of *Douglas-Hamilton* (U.S. Patent No. 4,530,816), and claim 5 presently stands rejected in the Office Action under 35 U.S.C. §103 as allegedly being unpatentable over *Johnson* in view of *Hjertstrand* (U.S. Patent No. 4,145,895). Further, claims 22-27 have been newly added via the amendments set forth herein. Applicants submit that the pending dependent claims 2-5 and 22-27 contain all features of their respective independent claim 1. Since claim 1 should be allowed, as argued hereinabove, pending dependent claims 2-5 and 22-27 should be allowed as a matter of law for at least this reason. *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988).

Claim 6

Claim 6 presently stands rejected under 35 U.S.C. §103 as allegedly being unpatentable over *Johnson* in view of *Hjertstrand*. Claim 6 reads as follows:

6. A method, comprising the steps of:
providing a container;
positioning a biological material within the container; and
placing a phase change material in close proximity to the biological material such that a temperature of the biological material is maintained near a phase change temperature of the phase change material, the phase change material composed of a mixture of water and deuterium oxide such that the phase change temperature is above zero degrees Celsius and below 3.8 degrees Celsius. (Emphasis added).

Applicants respectfully assert that the combination of *Johnson* and *Hjertstrand* fails to suggest at least the features of claim 6 highlighted hereinabove. Thus, the 35 U.S.C. §103 rejection of claim 6, as amended, is improper.

In this regard, Applicants observe that neither *Johnson* nor *Hjertstrand* suggests a mixture of deuterium oxide and water having a phase change temperature above zero degrees Celsius and below 3.8 degrees Celsius. In particular, *Johnson* suggests the use of a mixture of deuterium oxide and water but specifically teaches that the mixture is to have a phase change temperature between negative (-) 4 degrees Celsius and 0 degrees Celsius. See column 2, lines 65-68. Further, *Hjertstrand* apparently suggests the use of various phase change materials for maintaining a material at a desired temperature. However, *Hjertstrand* fails to provide any reason or motivation for using a mixture of water and deuterium oxide in lieu of the materials specifically suggested therein. Accordingly, the combination is inadequate to suggest “placing a phase change material in close proximity to the biological material such that a temperature of the biological material is maintained near a phase change temperature of the phase change material, ***the phase change***

material composed of a mixture of water and deuterium oxide such that the phase change temperature is above zero degrees Celsius and below 3.8 degrees Celsius,” as recited by amended claim 6. (Emphasis added).

Furthermore, when a claimed invention is rejected under 35 U.S.C. §103 by combining the teachings of multiple prior art references, “(t)here must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination.” *In re Oetiker*, 977 F.2d 1443, 1447, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992).

Applicants respectfully assert that the cited art fails to provide a sufficient reason, suggestion, or motivation for combining the select teachings of *Johnson* and *Hjertstrand*, and the 35 U.S.C. §103 rejection of claim 6 is improper for at least this reason.

In this regard, in rejecting claim 6, it is asserted in the Office Action that:

“It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the phase change material of Johnson with the container of Hjertstrand et al. because deuterium oxide enables the container to maintain the specific temperature range of approximately 0-5 degrees Celsius.”

However, Applicants observe that the material of *Johnson* does not maintain the specific range of approximately 0-5 degrees. Instead, *Johnson* specifically teaches that a temperature range between negative (-) 4 degrees Celsius and 0 degrees Celsius is maintained. See column 2, lines 65-68.

Moreover, the Office Action fails to establish that the cited art provides a sufficient reason or motivation for combining the select teachings of *Johnson* and *Hjertstrand* and, therefore, fails to establish a *prima facie* case of obviousness. “Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.” *In re Dembiczak*, 175 F.3d 994, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999).

Furthermore, where there is no apparent disadvantage present in a particular prior art reference, then generally there can be no motivation to combine the teaching of another reference with the particular prior art reference. *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349, 53 U.S.P.Q.2d 1580 (Fed. Cir. January 27, 2000). Applicants submit that there is no apparent deficiency in *Hjertstrand* or *Johnson* that would motivate one of ordinary skill in the art to combine the select teachings of any one of the references with the other. Indeed, it appears that the specific phase change materials suggested by *Hjertstrand* sufficiently enable temperatures in the container to be maintained within the alleged range (*i.e.*, 0 to 5 degrees Celsius), and there is no apparent reason for one of ordinary skill in the art to seek the “freeze indicator” teachings of *Johnson* when implementing the container described by *Hjertstrand*.

In addition, since *Johnson* teaches a temperature range (*i.e.*, negative (-) 4 degrees Celsius to 0 degrees Celsius) outside of the acceptable temperature range suggested by *Hjertstrand*, Applicants submit that *Johnson* teaches away from and, therefore, should not be combined with the teachings of *Hjertstrand*.

For at least the above reasons, Applicants respectfully assert that the alleged combination of *Johnson* and *Hjertstrand* is improper. Further, the combination also fails to suggest each feature of claim 6. Therefore, the 35 U.S.C. §103 rejection of claim 6 should be withdrawn.

Claim 7

Claim 7 presently stands rejected under 35 U.S.C. §103 as allegedly being unpatentable over *Johnson* in view of *Hjertstrand*. Claim 7 reads as follows:

7. A method, comprising the steps of:
mixing water and deuterium oxide thereby forming a mixture, wherein the mole fraction of deuterium oxide is selected so the mixture has a desired phase change temperature in a range above zero degrees Celsius and below 3.8 degrees Celsius; and
placing the mixture close to a biological material so that a temperature of the biological material is maintained at the desired phase change temperature.
(Emphasis added).

For at least reasons similar to those set forth above in the arguments for allowance of claim 6, Applicants respectfully assert that the combination of *Johnson* and *Hjertstrand* fails to suggest at least the features of claim 7 highlighted hereinabove, and Applicants submit that the combination of *Johnson* and *Hjertstrand* is improper. Thus, the 35 U.S.C. §103 rejection of claim 7, as amended, should be withdrawn.

Claim 8

Claim 8 presently stands rejected in the Office Action under 35 U.S.C. §103 as allegedly being unpatentable over *Johnson* in view of *Hjertstrand*. Applicants submit that the pending dependent claim 8 contains all features of its independent claim 7. Since claim 7 should be allowed, as argued hereinabove, pending dependent claim 8 should be allowed as a matter of law for at least this reason. *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988).

Claim 10

Claim 10 presently stands rejected under 35 U.S.C. §102 as allegedly being anticipated by *Johnson*. Claim 10 reads as follows:

10. A treatment pack for use in physical therapy in order to maintain live tissue within a desired temperature range, comprising:
a pack for holding phase change material; and
a mixture of water and deuterium oxide having a selected mole fraction of deuterium oxide for a desired phase change temperature in a range above zero degrees Celsius and below 3.8 degrees Celsius, wherein the mixture is placed within the pack. (Emphasis added).

For at least reasons similar to those set forth above in the arguments for allowance of claim 1, Applicants respectfully assert that *Johnson* fails to disclose at least the features of claim 10 highlighted hereinabove. Thus, the 35 U.S.C. §102 rejection of claim 10, as amended, is improper and should be withdrawn.

Claims 11-13

Claims 11 and 12 presently stand rejected in the Office Action under 35 U.S.C. §102 as allegedly being anticipated by *Johnson*. In addition, claim 13 presently stands rejected in the Office Action under 35 U.S.C. §103 as allegedly being unpatentable over *Johnson* in view of *Douglas-Hamilton*. Applicants submit that the pending dependent claims 11-13 contain all features of their respective independent claim 10. Since claim 10 should be allowed, as argued hereinabove, pending dependent claims 11-13 should be allowed as a matter of law for at least this reason. *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988).

Claim 17

Claim 17 presently stands rejected in the Office Action under 35 U.S.C. §103 as allegedly being unpatentable over *Johnson*. Applicants submit that the pending dependent claim 17 contains all features of its independent claim 15. Since claim 15 is allowable, as indicated hereinbelow, pending dependent claim 17 should be allowed as a matter of law for at least this reason. *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988).

Claim 21

Claim 21 presently stands rejected under 35 U.S.C. §102 as allegedly being anticipated by *Johnson*. Claim 21 reads as follows:

21. A method, comprising the steps of:
providing water;
selecting an amount of deuterium oxide to be mixed with the water *such that a mixture composed of the selected amount of deuterium oxide and the water has a phase change temperature close to a desired temperature in a range above zero degrees Celsius and below 3.8 degrees Celsius*; and
mixing the water and the selected amount of deuterium oxide thereby forming a phase change material; and
positioning the phase change material close to a biological material such that a temperature of the biological material is controlled by the phase change material. (Emphasis added).

For at least reasons similar to those set forth above in the arguments for allowance of claim 1, Applicants respectfully assert that *Johnson* fails to disclose at least the features of claim 21 highlighted hereinabove. Thus, the 35 U.S.C. §102 rejection of claim 21, as amended, is improper and should be withdrawn.

Allowable Subject Matter

Claims 15 and 16 have been indicated as allowable by the outstanding Office Action if such claims are rewritten to include the limitations of their respective base claims. Accordingly, pending claims 15 and 16 have been amended herein to include the features of their respective base claim 14, and Applicants respectfully request that the objections to claims 15 and 16 be withdrawn.


CONCLUSION

Applicants respectfully request that all outstanding objections and rejections be withdrawn and that this application and all presently pending claims be allowed to issue. If the Examiner has any questions or comments regarding Applicants' response, the Examiner is encouraged to telephone Applicants' undersigned counsel.

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